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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/171,607	11/04/98	FORSSMANN W	P63132US0

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JACOBSON PRICE HOLMAN & STERN
400 SEVENTH STREET NW
WASHINGTON DC 20004

EXAMINER	
DECLOUX, A	
ART UNIT	PAPER NUMBER
1644	15

DATE MAILED: 10/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/171,607	Forssmann et al.
Examiner	**Art Unit**
DeCloux, Amy	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *9-14-00 and 12-26-00*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-21* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-21* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

The request filed on 9-14-00 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/171,607 is acceptable and a CPA has been established. An action on the CPA follows.

1. The claim to priority to PCT/EP97/02012, filed 4/22/97, disclosed in the Oath/Declaration, needs to be included as the first sentence of the specification following the title, preferably as a separate paragraph.

2. The claim to foreign priority in document FRG 19615710 , filed 4/22/96, disclosed in the Oath/Declaration, is not granted since MPEP 201.13 C requires that there be the same inventive entity in the U.S. and the foreign priority country. Ludger Staendker is not named as an inventor on said foreign priority document.

3. The CRF submitted by the applicant (1/20/00) has been corrected by the STIC Systems Branch as follows: 1) changed a file from non-ASCII to ASCII, 2) changed the margins in cases where the sequence text was "wrapped" down to the next line, 3) added the mandatory headings and subheadings for "Current Application Data", 4) deleted non-ASCII "garbage" at the end of files.

4. Claim 1 is objected to because of the following informality:
Claim 1 recites an amino acid sequences that is not identified by its corresponding SEQ ID NO. The applicants are required to recite the appropriate SEQ ID NO in the claims. Also, a sequence is disclosed in the specification on page 3 which is not identified by a corresponding SEQ ID NO. Applicant is required to insert "SEQ ID NO:1" after both of these sequences.

5. The reference DE 3633797 A1, cited in the in the PTO Form 1449 and initialed by the Examiner, was not considered, since an English translation was not provided. If applicants wish to have said reference considered, a translation in English should be supplied to the office.

6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: antecedent basis is lacking for the phrase "pharmacologically active" recited in claims 3-6, 8, 10-14 and 16-21, for the phrase "electrolytic activity" recited in claim 17, and pharmacologically compatible" recited in claim 1 and dependent claims 2-21. It is suggested that the Applicants amend the specification to include this limitation, in order to overcome this rejection.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-10 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for a peptide consisiting of HF-COLL-18/514cf as recited in claim 1, a processs for the preparation of HF-COLL-18/514cf, as recited in claims 3-5, medicants comprising the peptide consisting of HF-COLL-18/514cf as recited in claims 6-7, for antibodies reactive with HF-COLL-18/514cf as recited in claim 8, for a method of treatment by the administration of HF-COLL-18/514cf as recited in claims 9-10, and for a diagnostic agent comprising an antibody to HF-COLL-18/514cf as recited in claim 20 , does not reasonably provide enablement for the inventions of the instant claims that encompass a any "natural and pharmacollogically active derivative" of HF-COLL-18/514cf or any fragment of either HF-COLL-18/514cf or a derivative thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, unpredictability in the art, the amount of experimentation required, and the amount of direction or guidance presented.

The instant claims are drawn to a peptide consisiting of HF-COLL-18/514cf and natural and pharmacollogically active derivative thereof, and fragments thereof, as recited in claims 1-2, a processs for the preparation of HF-COLL-18/514cf and pharmacollogically active fragments thereof, as recited in claims 3-5, medicants comprising the peptide consisting of HF-COLL-18/514cf and pharmacollogically active fragments thereof, as recited in claims 6-7, for antibodies reactive with HF-COLL-18/514cf and pharmacollogically active fragments thereof, as recited in claim 8, for a

method of treatment by the administration of HF-COLL-18/514cf and pharmacollogically active fragments and derivatives thereof, or an antagonist/inhibitor of HF-COLL-18/54cf as recited in claims 9-10, and for a diagnostic agent comprising an antibody to HF-COLL-18/514cf and pharmacollogically active fragments thereof, and HF-COLL-18/514cf and pharmacollogically active fragments thereof as recited in claim 20. However, the specification does not enable one of skill in the art regarding how to make and or use any antagonist/inhibitor of HF-COLL-18/54cf as recited in the instant claims, except for an antibody against HF-COLL-18/514cf, nor how to make and use any pharmacollogically active fragments of HF-COLL-18/514cf, nor how to make and use any pharmacollogically active derivatives of HF-COLL-18/514cf. There is insufficient guidance and direction provided in the specification on how to identify any fragments containing the active portions of HF-COLL-18/514cf, nor which of innumerable derivatives, known and unknown, would be pharmocollogically active. Also, there is insufficient guidance and direction provided in the specification that any antagonist/inhibitor of HF-COLL-18/54cf is efficacious in a method for the treatment of patients as recited in Claim 10. Based upon the paucity of information contained within the instant specification in this regard, it would require an undue amount of experimentation on the part of one skilled in the art to make and or use any antagonist/inhibitor of HF-COLL-18/54cf as recited in the instant claims, except for an antibody against HF-COLL-18/514cf, nor how to make and use any pharmacollogically active fragments of HF-COLL-18/514cf, nor how to make and use any pharmacollogically active derivatives of HF-COLL-18/514cf, encompassed by the instant claims.

In view of the quantity of experimentation necessary to use the claimed invention, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

9. *35 U.S.C. § 101* reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 11-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11-19 provide for the use of medicants where the instant claims recite a method of treatment of diseases of the human organism, but since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 11-19 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

12. Claims 1-21 are rejected under *35 U.S.C. § 112*, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

A) Claims 2-8, 10-14 and 16-21 lack an antecedent basis in the recitation of " pharmacologically active" and "pharmacologically compatible".

B) Claim 2-8, 10-14 and 16-21 are indefinite in the recitation of pharmacologically active" and "pharmacologically compatible" because it is not clear exactly how the phrases are defined.

C) Claims 3-4 are indefinite in their recitation of a process for the preparation of the peptide because the process does not clearly set forth method steps and there is an absence of a resolution step.

D) Claim 3 is indefinite in its recitation of "characterized in that" because it is not clear how said phrase modifies said process. Please clarify.

E) Claim 17 is indefinite in its recitation of "electrolytic activity" because it is not clear what said phrase means. Please clarify.

F) Claim 17 lacks an antecedent basis in the recitation of "electrolytic activity".

G) Claim 17 is indefinite in its recitation of "treatment of systemic diseases <u>in an</u> overproduction or deficiency of HF-COLL-18/514cf" (underline added) because it is not

clear what "in an " means, possibly it means "with". Please clarify.

H) Claims 20-21 are indefinite in their recitation of a diagnostic agent because it is not clear what the agent is capable of diagnosing and accordingly, there is an absence of a resolution step.

I) Claims 1, 11-14 and 16 are indefinite in its recitation of " especially" because said term is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining what is special, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

J) Claim 15 is indefinite for being in improper Markush format. The Office recommends setting off the last member by an --or--, not "and".

K) Claim 5 is indefinite it its recitation of "common methods" because it is not clear which methods exactly are being described.

L) Claim 5 is indefinite in its recitation of the phrase "per se known" because it is not clear exaclty what said phrase means.

M) Claim 6 is indefinite in its recitation of "usual" because it is not clear which "usual" excipients and additives are being described.

N) Claim 21 is indefinite in its recitation of "certain" because it is not clear which "certain" carcinoses are being descrribed.

13. SEQ ID NO:1 which encodes the peptide HF-COLL-18/514cf appears to be free of prior art.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform

with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner,
Group 1640, Technology Center 1600
October 9, 2001

David A. Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644